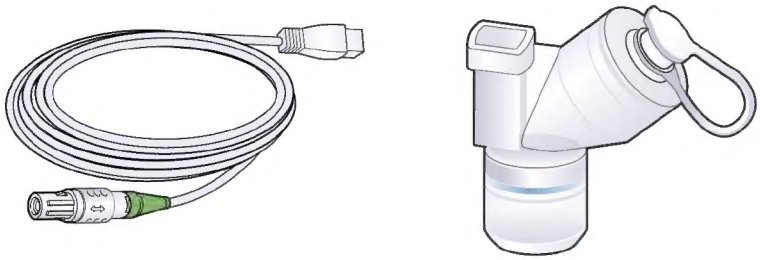

Aerogen Solo

Instructions for Use

REF AGAS3010, AGAS3020, AGAS3035, AGAS3036, AGAS3075, AGAS3085, AGAS3100, AGAS3450, 159566 (AGIB1100HM)

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HAMILTON MEDICAL

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Preface

Be sure to read the documentation before using the device or accessories.

Documentation downloads

To download the latest version of this manual or other documents, visit the Hamilton Medical Resource Center: https://www.hamilton-medical.com/Resource-center

Training

Hamilton Medical offers the Hamilton Medical e-Academy, which provides a variety of learning modules free of charge. To register, go to: https://e-academy.hamilton-medical.com

Conventions used in this guide

In this manual:

- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.
  ① These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts.
  Ⓐ These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

Safety messages are displayed as follows:

⚠ WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

⚠ CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTICE

Emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

⚠ WARNING!

⚠ CAUTION!

NOTICE!

1 Safety information

This chapter provides safety information related to setting up and operating the Aerogen Solo nebulizer.

Be sure to also read the safety information for nebulization with the ventilator, provided in the ventilator *Operator's Manual*.

Review the *Instructions for Use* before using the nebulizer and accessories.

Only trained medical personnel may use these devices.

If you have questions about any of the information in this manual, contact your Hamilton Medical representative or technical service personnel.

See the following sections for safety information that applies to:

- General use, including use with an HMEF
- Aerogen Solo

Regional approvals

In certain regions it is *not* permitted to use the Aerogen Solo nebulizer as follows:

Between the HMEF and endotracheal tube:	
Brazil	China
Japan	Russia
With a tracheostomy tube:	
Brazil	China
Japan	Russia
USA	

During noninvasive ventilation:	
Brazil	China
Japan	Russia

1.1 General safety information

⚠ WARNING

- Inspect all parts before use, and do *not* use if any parts are missing, cracked, or damaged. In case of missing parts, malfunction, or damage, contact your Hamilton Medical technical service personnel.
- Only use physician-prescribed solutions that are approved for use with a general purpose nebulizer. Consult the drug manufacturer's instructions regarding suitability for nebulization.
- Use only with components, connectors, and accessories that are specified by Aerogen in these *Instructions for use* and in the Aerogen documentation (available at www.aerogen.com).
- Do *not* use in the presence of flammable substances or flammable anesthetic mixtures combined with air, oxygen, or nitrous oxide.
- To avoid the risk of fire, do *not* use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air under high pressure.
- Do *not* modify this equipment without the authorization of the manufacturer.
- Do *not* use or store outside of specified environmental conditions.

- To avoid damage to the nebulizer:

  – Do *not* apply undue pressure to the domed aperture plate in the center of the nebulizer.

  – Do *not* use a syringe with a needle to add medication.

  – Do *not* push out the Aerogen Vibronic aerosol generator.
- During use, observe for correct functioning of the nebulizer by regularly verifying aerosol is visible.
- Condensate can collect and occlude the breathing circuit. Always position the breathing circuit so that fluid condensate drains away from the patient.
- To avoid exhaled medication affecting the ventilator, follow the ventilator manufacturer's recommendations for use of a bacterial filter in the expiratory limb of the breathing circuit.

1.1.1 HMEF-related safety information

⚠ WARNING

- Do *not* use a filter or HMEF between the nebulizer and the patient airway.
- Only use with HMEF devices for which the manufacturer's instructions allow use with a nebulizer, and always follow the HMEF manufacturer's instructions.
- Always monitor the resistance to flow and excessive rain-out, and change the HMEF device as per manufacturer's instructions.
- Ensure that the total combined volume of the nebulizer, T-piece, and HMEF is suitable for the tidal volume being delivered and does *not* increase dead space to the extent that it adversely impacts the ventilatory parameters of the patient.

  Note the volume contributed by the T-piece:
  T-piece volume, Adult: 34.3 ml
  T-piece volume, Pediatric (OD15/ID15): 19.5 ml

1.1.2 Tracheostomy-related safety information

⚠ WARNING

- The combined weight of the tracheostomy tube assembly, nebulizer, and T-piece configuration may cause accidental decannulation.
- Ensure that the total combined volume of the nebulizer, T-piece, and tracheostomy tube assembly is suitable for the tidal volume being delivered, and does not increase the dead air space to the extent that it adversely impacts the respiratory parameters of the patient.

1.2 Aerogen Solo-specific safety information

⚠ WARNING

- *(USA only)* Federal law restricts this device to sale by or on the order of a physician.
- The Aerogen Solo nebulizer is a single patient use device to be used only on one patient to prevent cross infection.
- The Aerogen Solo components and accessories, as packaged, are *not* sterile.
- The Aerogen Solo components and accessories are *not* made with natural rubber latex.
- Do *not* use the Aerogen Solo nebulizer beyond the defined lifetime of the device (Section 5.5).
- Use of the Aerogen Solo and T-piece during the administration of volatile anesthetics may result in adverse effects on the constituent plastics. Do not use with volatile anesthetics unless known to be compatible.
  Aerogen has determined that, using anesthetic ventilators, the following anesthetic agents are compatible at the below listed maximum concentrations and conditions:
  – Maximum duration of exposure: 12 hours
  – Isoflurane (FORANE): 3.5%
  – Sevoflurane (SEVOFLURANE): 8%
  – Desflurane (SUPRANE): 10%

NOTICE

- Connection of the Aerogen Solo nebulizer on the patient side of a Y-piece is *only* approved for use in the USA.
- *(HAMILTON-C6 only)* Aerogen Solo operates continuously during active ventilation when the **Nebulization** function is activated. For nebulization details, see your ventilator *Operator's Manual*.

2 Overview

NOTICE

- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

This guide provides information about the use and set up of Aerogen Solo nebulizer with Hamilton Medical ventilators. It is designed for use together with your ventilator *Operator's Manual*, and may refer to information provided therein.

Certain Hamilton Medical ventilators support nebulization using the Aerogen Solo nebulizer as an option.

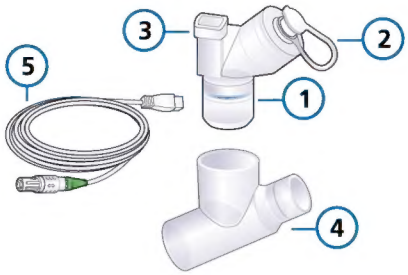
The system comprises the ventilator hardware with **Aerogen** port/module on the ventilator, and an Aerogen nebulizer with T-piece/adapters and connection cable.

2.1 About the Aerogen Solo nebulizer

The Aerogen Solo nebulizer[1] comprises the nebulizer, T-piece, optional breathing circuit adapters, and connection cable.

Figure 1 shows the Aerogen Solo system components. Table 1 provides T-piece and adapter size specifications.

Figure 1. Aerogen Solo nebulizer components



1 Aerogen Solo nebulizer
2 Filler cap
3 Cable connection port
4 T-piece
5 Connection cable to ventilator

Optional adapters and ventilator hardware not shown.

2.2 About the breathing circuits and nebulizer components

To connect the nebulizer to the breathing circuit, a variety of T-pieces and adapters are available.

This section lists parts available for the Aerogen Solo (Table 1) nebulizer.

For more information on breathing circuits, see your ventilator *Operator's Manual*.

Table 1. Aerogen Solo T-piece and adapter specifications

Part number	Patient Group	Specification
AGAS3010	Adult	ID22 / ID22 / OD22
AGAS3020	Pediatric	ID15 / ID22 / OD15
AGAS3035	Neonatal	ID12 / ID22 / OD12
AGAS3036	Neonatal	ID10 / ID22 / OD10

For more information on T-pieces and adapters, see the e-catalog on the Hamilton Medical website: https://www.hamilton-medical.com/Products/Accessories-and-Consumables/E-catalog.html.

[1] *(USA only)* Aerogen Solo is not approved for use with patients younger than 28 days old.

3 Working with the nebulizer

Before proceeding, review the safety information in Section 1.

Setting up the nebulizer comprises the following steps.

Table 2. Nebulizer setup overview

To ...	See ...
Enable Aerogen nebulization on the ventilator	Your ventilator *Operator's Manual*
Perform the functional test	Section 3.1
Connect the Aerogen Solo nebulizer to the breathing circuit	Section 3.2
Connect the nebulizer cable to the ventilator	Section 3.3
Add medication	Section 3.4

3.1 Performing a functional test

Perform a functional test of the nebulizer:

- Prior to first use
- At any time to verify proper operation

To perform the nebulizer functional test

For details on performing tasks on the ventilator, see your ventilator *Operator's Manual*.

1. Visually inspect the nebulizer and each accompanying component for cracks or damage, and replace if any defects are visible.
2. Pour 1 to 6 ml of normal saline solution (0.9%) into the Aerogen Solo nebulizer.
3. Connect the nebulizer to the Aerogen port/module on the ventilator using the connection cable.
4. Turn on the ventilator and ensure Aerogen nebulization is enabled.
5. Start nebulization on the ventilator.
6. Perform a visual aerosol check by verifying that aerosol is visible during nebulization.

When aerosol is visible, the test is successful and the nebulizer is ready for use.

If aerosol is not visible, troubleshoot as described in Table 3.

Table 3. Troubleshooting: **Aerosol is not visible**

Possible causes	Action needed
There is no medication in the nebulizer.	Refill the medication through the filler cap of the nebulizer.
The cable connection to the ventilator is faulty.	Disconnect and reconnect the cable between the nebulizer and the ventilator.
The incorrect nebulization option is configured on the ventilator.	Verify that Aerogen is selected in Configuration, as described in your ventilator *Operator's Manual*.
The nebulizer is faulty.	Replace the nebulizer.

3.2 Connecting Aerogen Solo to the breathing circuit

Before proceeding, review the safety information in Section 1.

Use of the Aerogen Solo nebulizer with an HMEF is contraindicated for neonatal patients.

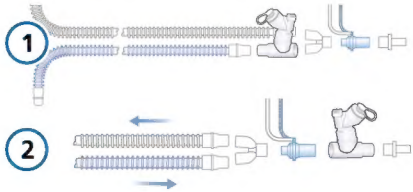
You can connect Aerogen Solo to the breathing circuit using any of the following methods.

Table 4. Aerogen Solo connection options

To connect ...	See ...
To the inspiratory limb	Section 3.2.1
To the dry side of the humidifier	*Nebulizer Positioning Guidelines* and Aerogen documentation
After the Y-piece[1] (without humidification)	Section 3.2.2
To a tracheostomy tube	Section 3.2.3

For additional connection details, see the *Nebulizer Positioning Guidelines* (ELO2020-124-TW), available in the Hamilton Medical Resource Center (https://www.hamilton-medical.com/Resource-center), and the manufacturer's *Instructions for use*.

Figure 2. Aerogen Solo connection options



1 Inspiratory limb connection

2 After the Y-piece connection

Adapters and dry-side of the humidifier connection not shown.

[1] Only approved for use in the USA.

3.2.1 Connecting Aerogen Solo to the inspiratory limb

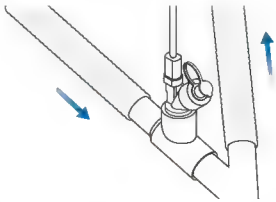
You can connect Aerogen Solo to the inspiratory limb of the breathing circuit, with or without humidification. The connection is the same in both cases.

Before proceeding, perform the functional test on the nebulizer (Section 3.1).

To connect to an adult breathing circuit

1. Connect the nebulizer to the adult T-piece (Table 1).
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit in front of the Y-piece (Figure 3).
3. Connect the nebulizer cable to the Aerogen port/module on the ventilator (Section 3.3).

Figure 3. Connecting Aerogen Solo to the inspiratory limb of the breathing circuit (adult circuit shown)



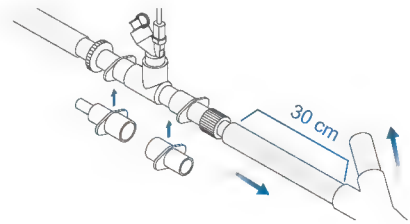
To connect to a pediatric breathing circuit

1. Connect the nebulizer to the pediatric T-piece, and if required, neonatal adapters (Table 1).
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit (Figure 3 or 4).
3. Connect the nebulizer cable to the Aerogen port/module on the ventilator (Section 3.3).

To connect to a neonatal breathing circuit[1]

1. Connect the nebulizer using either of the following:
   – Neonatal T-piece
   – Pediatric T-piece and neonatal adapters
   For specifications, see Table 1.
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit, approximately 30 cm away from the patient Y-piece (Figure 4). The 30 cm distance allows for placement of the nebulizer outside of an incubator.
3. Connect the nebulizer cable to the Aerogen port/module on the ventilator (Section 3.3).

Figure 4. Connecting Aerogen Solo with adapters to the inspiratory limb of the breathing circuit



[1] *(USA only)* Aerogen Solo is not approved for use with patients younger than 28 days old.

3.2.2 Connecting Aerogen Solo after the Y-piece

Before proceeding, review the safety information in Section 1.

You can connect Aerogen Solo to the breathing circuit after the Y-piece, with or without an HMEF.[1]

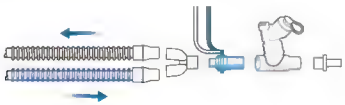
If using an HMEF, be sure to read the safety information in Section 1.1.1.

Before proceeding, perform the functional test on the nebulizer (Section 3.1).

To connect Aerogen Solo after the Y-piece

1. If using an HMEF, connect it to the patient end of the breathing circuit.
2. Connect the flow sensor to the HMEF, if used; if not, connect the flow sensor to the patient end of the breathing circuit.
3. Connect the nebulizer to the appropriate T-piece and any required adapters.
4. Connect the T-piece and nebulizer to the flow sensor (Figure 5).
5. Connect the nebulizer cable to the Aerogen port/module on the ventilator (Section 3.3).

Figure 5. Connecting Aerogen Solo after the Y-piece



3.2.3 Connecting Aerogen Solo to a tracheostomy tube

Before proceeding, review the safety information in Section 1.

Use of the Aerogen Solo nebulizer with a tracheostomy tube is contraindicated for neonatal patients.

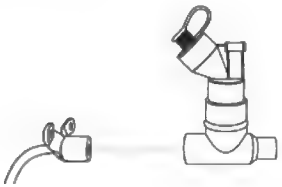
The Aerogen Solo nebulizer is compatible with standard tracheostomy tubes.

To connect Aerogen Solo to a tracheostomy tube

1. Connect the nebulizer to the T-piece.
2. Connect the T-piece to the tracheostomy tube assembly (Figure 6).
3. If needed, attach an extension piece so that the nebulizer can be placed on an adjacent surface.

   The additional weight of the Aerogen Solo nebulizer may cause accidental decannulation.

Figure 6. Connecting Aerogen Solo to a tracheostomy tube



[1] Use of the Aerogen Solo nebulizer with an HMEF is contraindicated for neonatal patients.

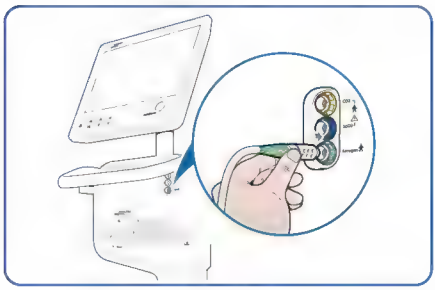
3.3 Connecting the nebulizer to the ventilator

After connecting the nebulizer to the breathing circuit, you must connect it to the ventilator. During nebulization, the ventilator powers and controls the nebulizer.

To connect the nebulizer to the ventilator

1. Insert the connection cable into the port on the nebulizer (Figure 1).
2. Connect the other end of the cable to the Aerogen port/module on the ventilator (Figure 7).

Figure 7. Connecting the nebulizer to the ventilator



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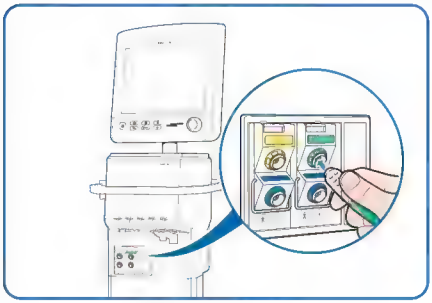

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3.4 Adding medication to the nebulizer

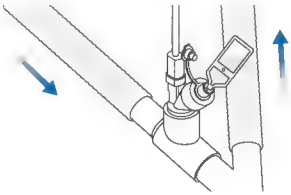
You can add medication during nebulization without interrupting operation or ventilation.

To add medication to the nebulizer

1. Open the filler cap on the nebulizer.
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer (Figure 8).
3. Close the filler cap.

Do *not* fill the Aerogen Solo nebulizer beyond its maximum capacity of 6 ml.

Figure 8. Adding medication to the Aerogen Solo nebulizer using a pre-filled ampoule



4 Maintenance

The Aerogen Solo nebulizer is a single patient use device, and therefore maintenance and cleaning are not permitted.

⚠ WARNING

Do *not* autoclave any Aerogen Solo components or accessories.

NOTICE

Aerogen Solo and its accessories are approved for single patient use only, and are *not* intended to be cleaned, disinfected, or sterilized.

5 Specifications

This section describes the Aerogen Solo intended use, performance specifications, lifetime, and warranty.

Additional information and specifications are available at the Aerogen website, www.aerogen.com.

5.1 Intended use

Rest of the world (ROW)

The Aerogen Solo nebulizer is part of the Aerogen Solo System, an iteration of the Aerogen Pro System. It is intended for hospital use only to nebulize physician-prescribed medications for inhalation approved for use with a general purpose nebulizer.

The Aerogen Solo nebulizer is for single patient use only. The Aerogen Solo System is suitable for intermittent and continuous nebulization of neonate, pediatric and adult patients as described in this guide. In the home care environment, the system is suitable for intermittent nebulization only.

It is intended for on and off ventilation, or other positive pressure breathing assistance in the hospital environment, and for on ventilation only in the home care environment.

USA

The Aerogen Solo nebulizer is a portable medical device for single patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aerogen Solo is suitable for intermittent and continuous nebulization of pediatric (29 days or older) and adult patients as described in this guide.

5.2 Physical characteristics

Table 5. Aerogen Solo physical characteristics

Nebulizer dimensions		57 mm (H) x 48 mm (W) x 25 mm (D) 2.6 in (H) x 1.88 in (W) x 1.1 in (D)
Nebulizer weight		13.5 g (0.5 oz) nebulizer and plug
T-piece weight	Adult	28.7 g (1.0 oz) T-piece and plug
	Pediatric	16.8 g (0.6 oz) T-piece and plug
	Neonatal	14 g (0.5 oz) T-piece and plug
Nebulizer capacity		Maximum 6 ml
T-piece volume	Adult	34.3 ml
	Pediatric (15 mm)	19.5 ml

5.3 Performance specifications

Table 6 shows the results of aerosol performance testing for the Aerogen Solo using an 8 stage cascade impactor running at a continuous flow rate of 28.3 LPM. Indicated ranges correspond to confidence intervals with a confidence level of 95%.

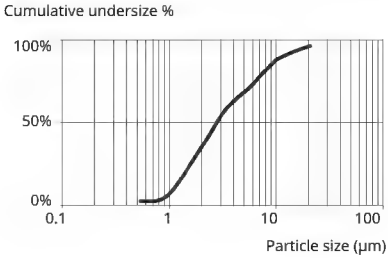
Table 6. Aerogen Solo performance specifications

Flow rate	> 0.2 ml/min (average ~ 0.38 ml/min)
Particle size	**As per EN 13544-1** Aerosol output rate: 0.30 ml/min Aerosol output: 1.02 ml emitted of 2.0 ml dose Residual volume: < 0.1 ml for 3 ml dose **As measured with the Andersen Cascade Impactor** Specification range: 1 to 5 µm Average tested: 3.1 µm **As measured with the Marple 298 Cascade Impactor**[1] Specification range: 1.5 to 6.2 µm Average tested: 3.9 µm

Performance may vary depending on the type of drug and nebulizer used. For additional information, contact Aerogen or the drug supplier.

The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.

Figure 9. Representative particle size distribution for Albuterol as per EN 13544-1



[1] Not applicable in the USA.

Table 7. Aerogen Solo aerosol performance testing

Element	Albuterol sulphate (1 mg/ml)	Ipratropium (0.25 mg/ml)	Budesonide (0.5 mg/ml)
Results obtained using an 8-stage cascade impactor running at a continuous flow rate of 28.3 l/min. Indicated ranges correspond to confidence intervals with a confidence level of 95%.			
Particle size (µm)	2.90 to 3.23	3.07 to 3.42	3.45 to 3.79
Geometric standard deviation (GSD)	2.09 to 2.35	1.80 to 1.93	1.92 to 2.14
Emitted dose (% of fill)	97.23 to 99.30	97.61 to 98.64	94.12 to 97.84
Respirable dose (0.5 to 5.0 µm) (% of fill)	67.66 to 73.50	71.78 to 76.69	62.32 to 66.90
Coarse particle dose (> 4.7 µm) (% of fill)	27.00 to 31.11	23.62 to 28.21	32.31 to 36.12
Fine particle dose (< 4.7 µm) (% of fill)	66.33 to 72.07	68.58 to 73.84	59.36 to 64.17
Ultra-fine particle dose (< 1.0 µm) (% of fill)	5.91 to 9.93	1.85 to 4.19	2.36 to 4.51

5.4 Environmental specifications

The Aerogen Solo nebulizer maintains specified performance at circuit pressures ≤ 88.25 hpa.

Table 8. Aerogen Solo environmental specifications

Temperature	Operating	5°C to 45°C (41°F to 113°F)
	Shipment / storage	-20°C to 60°C (-4°F to 140°F)
Atmospheric pressure	Operating	450 to 1100 hPa
	Shipment / storage	450 to 1100 hPa
Relative humidity	Operating	15% to 95%, noncondensing
	Shipment / storage	15% to 95%, noncondensing
Noise level	Operating	< 35 dB measured at 1.0 m
	Shipment / storage	N/a

5.5 Lifetime

As with all active electronic components, the Aerogen Solo nebulizer has a defined lifetime.

The lifetime of the Aerogen Solo nebulizer has been validated for intermittent use for a maximum of 28 days based on a typical usage profile of four (4) treatments per day.

For continuous use, the life of the Aerogen Solo nebulizer and the continuous nebulization tube set have been qualified for use for a maximum of 7 days.

Use in excess of this period is not qualified by Aerogen.

5.6 Warranty

Aerogen warrants that the Aerogen Solo nebulizer shall be free from defects of workmanship and materials for a period of the defined life of the nebulizer when used in accordance with these *Instructions for use*.

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